

EC Declaration of Conformity

Conformity to DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

Manufacturer: Greiner Bio-One GmbH
Bad Haller Straße 32
4550 Kremsmünster
Austria

Production Location: Greiner Bio-One GmbH
Bad Haller Straße 32
4550 Kremsmünster
Austria

Product / Product Group: VACUETTE® URINE TUBES (Stabilur)
(for details please refer to page 2)

Classification: Other device (all devices except Annex II and except self-testing devices)

GMDN Code(s): 58151

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the above EC Council Directive and the applicable standards. All supporting documentations are retained under the premises of the manufacturer.

Conformity Assessment procedure acc. to Annex III of the Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices.

Standards:

Refer to the List of applicable (harmonized) standards in the Technical Documentation.

Kremsmünster, 22.03.2021



Signature: 
Georg Sambs
Quality Manager GBO AT

PRODUCT GROUP	Product name - detailed product description	Item numbers
VACUETTE® URINE Stabilur TUBES	VACUETTE® TUBE 4 ml Urine Stabilur 13x75 yellow cap-red ring, Round Base, non-ridged	454463
VACUETTE® URINE Stabilur TUBES	VACUETTE® TUBE 10 ml Urine Stabilur 16x100 yellow cap-red ring, Round Base, non-ridged	455048
VACUETTE® URINE Stabilur TUBES	VACUETTE® TUBE 9 ml Urine Stabilur 16x100 yellow cap-red ring, Conical Base, non-ridged	455049
VACUETTE® URINE Stabilur TUBES	VACUETTE® TUBE 9.5 ml Urine Stabilur 16x100 yellow cap-red ring, KOH barcode label, Round base, non-ridged	485048
VACUETTE® URINE Stabilur TUBES	VACUETTE® TUBE 10 ml Urine Stabilur 16x100 yellow cap-red ring, Round Base, ISLAB barcode label, non-ridged	485148
VACUETTE® URINE Stabilur TUBES	VACUETTE® TUBE 10 ml Urine Stabilur 16x100 yellow cap-red ring, Round Base, ISLAB barcode label M, non-ridged	485148M